APR 0 7 2014

SPINEWAVE

510(k) Summary
Abacus™ Spacer System

1. Submitter Information

Submitter: Spine Wave, Inc.
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Shelton, CT 06484
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Contact: Joseph Mercado
Date Prepared: March 25, 2014

2. Device Information

Trade Name: Abacus™ Spacer System
Common Name: Intervertebral Body Fusion Device
Classification: Class II (special controls) per 21 CFR 888.3080
Classification Name: Intervertebral Fusion Device with Bone Graft, Lumbar
Product Code: MAX

3. Purpose of Submission

The purpose of this submission is to gain clearance for a new intervertebral body fusion device.

4. Predicate Device Information

The Abacus™ Spacer System described in this submission is substantially equivalent to the following predicates:

Predicate Device	Manufacturer	510(k) No.
StaXx® IBL System	Spine Wave, Inc.	K131071, K132719
CoRoent® System	NuVasive, Inc.	K071795

5. Device Description

The Abacus™ Spacer System is an intervertebral body fusion device manufactured from PEEK-OPTIMA (ASTM F2026) and includes tantalum markers (ASTM 560/ISO 13782). The Abacus™ Spacer System is available in a variety of shapes and sizes to accommodate variations in anatomy. The Abacus™ Spacer System is a rectangular-shaped device with a textured "tooth" pattern on both the superior and inferior surfaces designed to resist migration of the device once it is surgically positioned. The device also incorporates an internal cavity that allows for the placement of autograft material.

6. Intended Use

The Abacus™ Spacer System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-L5. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The Abacus™ Spacer System is to be used with autogenous bone graft and with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral body fusion device.

7. Comparison of Technological Characteristics

The substantial equivalence of the Abacus™ Spacer System to the predicates is shown by similarity in intended use, indications for use, materials and performance.

8. Performance Data

The following mechanical tests were performed to demonstrate the substantial equivalence of the Abacus™ Spacer System to its predicate:

- Static and dynamic axial compression (per ASTM F2077)
- Static and dynamic compression shear (per ASTM F2077)
- Subsidence (per ASTM F2267)

9. Conclusion

Based on the indications for use, technological characteristics, performance testing and comparison to the predicates, the Abacus™ Spacer System has been shown to be substantially equivalent to the predicate devices identified in this submission, and does not present any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 7, 2014

Spine Wave, Incorporated
Mr. Joseph Mercado
Regulatory Affairs Specialist
Three Enterprise Drive, Suite 210
Shelton, Connecticut 06484

Re: K140007
Trade/Device Name: Abacus™ Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: January 16, 2014
Received: January 17, 2014

Dear Mr. Mercado:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K140007

Device Name
AbacusTM Spacer System

Indications for Use *(Describe)*
The AbacusTM Spacer System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-L5. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The AbacusTM Spacer System is to be used with autogenous bone graft and with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral body fusion device.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anton E. Dmitriev, PhD

Division of Orthopedic Devices